

SUPPORT FOR THE AMENDMENTS

Claim 14 has been amended.

Support for the amendment to Claim 14 is found in Example 1 on page 4 of the specification as filed.

No new matter has been added.

REMARKS

Claims 1-18 are pending in the present application.

At the outset, Applicants wish to thank Examiner Sullivan and Examiner Richter for the helpful and courteous discussion with their undersigned Representative on March 3, 2010. During this discussion, Applicants' undersigned Representative presented the arguments in traverse of the outstanding rejections as summarized in the Interview Summary dated March 3, 2010. In view of these arguments and upon consideration of the same, the Examiners agreed with the undersigned and in the Interview Summary acknowledged that each of the rejections of record are withdrawn. For sake of completeness of the record, Applicants submit the following comments. The content of the March 3, 2010, discussion is reflected in the following comments. Reconsideration of the outstanding rejections is requested.

The rejection of Claim 14 under 35 U.S.C. §112, second paragraph, is respectfully traversed but, nonetheless, obviated by amendment. In view of the same, this indefiniteness rejection, including the amendment herein, has been withdrawn (see continuation sheet of the Interview Summary conducted March 3, 2010).

Applicants submit that there is nothing wrong with the previous expression of Claim 14. Indeed, the artisan would readily appreciate that the gabapentin and PEG concentration in the claimed composition can be adjusted to ensure that the total concentration of the two components does not exceed 100%. Nonetheless, Applicants have amend Claim 14 to define the concentration of gabapentin, based on Example 1 on page 4 of the specification, to be 70 to 98%. Applicants thank the Examiner for the indication that the foregoing argument is

persuasive and that this ground of rejection will be withdrawn (see March 3, 2010, Interview Summary).

Acknowledgement that this ground of rejection has been withdrawn is requested.

The rejection of Claims 1-18 under 35 U.S.C. §112, first paragraph (written description), has been indicated as being withdrawn (see continuation sheet of the Interview Summary conducted March 3, 2010).

For sake of completeness, Applicants remind the Examiner that the description in the specification need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient to support a claimed limitation (MPEP §2163). It is sufficient for support to be found implicitly so long as the artisan would appreciate that the description as would support the new limitation. In context, the Examples of the present application fully support the claim term “melt granulating” as the Examples relate to a melt granulation process (i.e., granulation carried out in the absence of granulating liquids; see, for example, Example 1 on page 4 of the specification).

Applicants thank the Examiner for recognizing the sufficiency of the description and indicating in the Interview Summary that this ground of rejection will be withdrawn. Applicants request acknowledgment to this effect.

The rejection of Claims 1-18 under 35 U.S.C. §112, first paragraph (enablement), has been indicated as being withdrawn (see continuation sheet of the Interview Summary conducted March 3, 2010).

For sake of completeness, Applicants point to the evidence provided with the response filed on August 24, 2009 (the MSDS sheet for polyethylene glycol available at

<http://www.jtbaker.com/msds/englishhtml/p5029.htm>). From this evidence and the description provided in the specification, the artisan would readily select PEG of the specified melting point range for use in the presently claimed invention without undue experimentation.

Applicants thank the Examiner for recognizing the enablement of the present invention and indicating in the Interview Summary that this ground of rejection will be withdrawn. Applicants request acknowledgment to this effect.

The rejections of:

- (a) Claims 1-6, 10-13, and 16-18 under 35 U.S.C. §102(b) over Spireas;
 - (b) Claims 5, 7-9 and 15 under 35 U.S.C. §103(a) over Spireas; and
 - (c) Claim 2-4 and 14 under 35 U.S.C. §103(a) over Spireas in view of Reo et al,
- have been indicated as being withdrawn (see continuation sheet of the Interview Summary conducted March 3, 2010).

For sake of completeness, Applicants remind the Examiner that Claims 1 and 12 share the following common features: “A gabapentin granulate obtained by *melt* granulating gabapentin with polyethylene glycol having a melting point comprised between 50 and 80°C”. As submitted in the response filed on August 24, 2009, it is clear that the claimed invention differs from the disclosure of Spireas et al at least with respect to the identity of the PEG employed. Spireas et al only disclose PEG 400. The melting point of PEG increases as molecular weight increases. As established by the evidence submitted on August 24, 2009, PEG 400 has a melting point of only about 4-8°C (see http://en.wikipedia.org/wiki/PEG_400 and the MSDS sheet for polyethylene glycol available at <http://www.jtbaker.com/msds/englishhtml/p5029.htm>). Clearly, when the claims are properly

examined to require that PEG having a melting point between 50 and 80°C to be incorporated in the gabapentin granulate, then Spireas et al fails to anticipate and/or render obvious the claimed invention, even when consideration is given to Reo et al.

Applicants thank the Examiner for recognizing that the claimed invention is not anticipated by or obvious in view of Spireas et al, with or without Reo et al, and indicating in the Interview Summary that these grounds of rejection will be withdrawn. Applicants request acknowledgment to this effect.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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